

MS Non-Fee Amendment
Attorney Docket No. 24222-X3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

S. CHERUKURI

(SUBRAMAN RAO CHERUKURI)

Serial No.: 09/982,093

Group Art Unit: 1615

Filed: October 19, 2001

Examiner: B. Fubara

For: DRUG DELIVERY SYSTEM

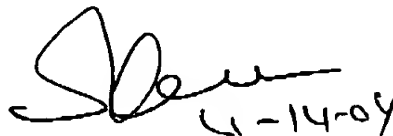
DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

NOW COMES the undersigned and declare that:

1. I, S. Rao Cherukuri, am a citizen of the United States.
2. That I hold a Masters in Science degree conferred upon me in pharmacy by Andhra University, vizag, india and Master of Business Administration degree from Wharton School of business, university of Pennsylvania.
3. That I am President and Chief Executive Office of Capricorn Pharma Inc., located at 6900 English Muffin Way, Unit A,


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CAPRICORN PHARMA

0003/006


Frederick, MD 21703. I am also the inventor of the subject matter under consideration in the captioned application.

4. That I have worked in the field of consumer health care and Pharmaceutical for over 35 years.

5. That I have reviewed amended claim 1 of U.S. Patent Application Serial No. 09/982,093 (the captioned U.S. patent application) and understand that the claim is drawn to a product consisting essentially of a therapeutically-effective amount of a pharmaceutical, at least one compressible material, and at least one lubricating material, wherein the product is in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters.

6. That the innovative aspect of the presently claimed invention is the small size of the finished product, namely the caplet having a diameter from about 1 mm to about 7 mm and a length from about 1 mm to about 7 mm.

7. That I have surprisingly determined that high doses of


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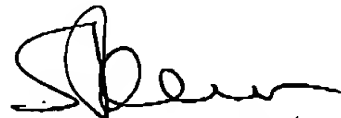
pharmaceuticals are able to be incorporated into the small product.

8. That the small size is critical for accurate, reproducible, multiple pluraty releases of delivery of the pharmaceutical when administered to a mammal. The same formulations incorporated into a larger product results in a different dose delivery profile, as the smaller caplet size increases the surface area of the delivery system, thus leading to better and more accurate delivery of the pharmaceutical to the mammal.

9. That the smaller size of the product provides faster dissolving of the caplets and thereby faster delivery of the pharmaceutical to the mammal.

10. That better accurate reproducible controlled dosing of pharmaceuticals has been desired in the healthcare industry, and the present inventive product provides better control via the smaller size of the dosing unit.

11. That I have reviewed U.S. Patent Nos. 6,197,828 and


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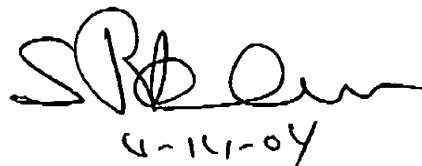
6,245,350, the prior art cited by the Examiner in rejecting the present claims. My review of the patents leads me to the conclusion that the inventive limitations of the captioned application, namely the small size of the inventive product, are not disclosed in either of the U.S. patents. Thus, neither cited patent provides the unique delivery characteristics of the present inventive subject matter.

12. It is, therefore, my opinion that one of ordinary skill in the art would not be lead to modify or improve either of the cited patents in an attempt to achieve the claimed invention based on the differences in the types of extracts as discussed herein.


13. All statements made herein of my own knowledge are true.

All statements made herein upon information and belief are believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both, under the provisions of 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing therefrom.

14. Further, declarants sayeth naught.


4-14-04

15. WITNESS my signature below in the indicated date.

4-14-2004 
Date S. Rao Cherukuri